IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
CORPUS CHRISTI DIVISION

VIOLA RESENDEZ and RAUL RESENDEZ, Plaintiffs, v. PFIZER, INC., JACQUELINE GUERRERO, BOB DAVIS, JEANNE L. JALUFKA, KYLE M. NELSON, JASON D. HAHN, ROBERT G. VIAL, KATHRYN K. TRUITT, KARI A. McLUHAN, REYNALDO RIOJAS, FRANCISCO MEZA, JACK BARINEAU, ERICA ZEPLIN, DEBORAH QUINONES, W. LANCE GOODSON, KEELY RODRIGUEZ, LEAH SILVA, DANIEL PONCE, CELESTE ESCOBAR, JILL GUIDRY, DANIEL TOWNSEND and LYNSEY ADAME, Defendants.	§ §	CIVIL ACTION NO. C-07-256 JURY REQUESTED *Pending Transfer to MDL-1699* (*In re Celebrex and Bextra Marketing, Sales Practices and Prods. Liab. Litig.*)

DEFENDANTS JEANNE L. JALUFKA, ROBERT G. VIAL, ERICA ZEPLIN, AND LYNSEY ADAME'S ORIGINAL ANSWER

TO THE HONORABLE JUDGE OF SAID COURT:

NOW COME Defendants Jeanne L. Jalufka, Robert G. Vial, Erica Zeplin, and Lynsey Adame (hereinafter "Defendants") and file this their Original Answer to Plaintiffs' Original Petition ("Complaint"), and would respectfully show the Court as follows:

PRELIMINARY STATEMENT

The Complaint does not include any sufficient allegations against Defendants. Counts one ("Strict Products Liability Failure to Warn"), two ("Strict Products Liability Defective Product"), three ("Negligence"), four ("Breach of Implied Warranty"), five ("Breach of Express Warranty"), six ("Fraud"), and seven ("Fraud by Concealment") of the Complaint merely assert

vague and conclusory allegations against "Defendants" generally, all of which fail as a matter of Texas law as to Defendants.

In addition, the Complaint does not state in sufficient detail when Plaintiff Viola Resendez was prescribed or used Celebrex® (celocoxib) ("Celebrex®"). Accordingly, this Answer can only be drafted generally. Defendants may seek leave to amend this Answer when discovery reveals the specific time periods in which Plaintiff was prescribed and used Celebrex®.

ORIGINAL ANSWER

I.

1. Answering the first unnumbered paragraph in Section I of the Complaint, Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required.

II.
Response to Introduction and Allegations Regarding Parties

2. Answering the first unnumbered paragraph in Section II of the Complaint, Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants admit that, during certain periods of time, Pfizer marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Celebrex® is a prescription medication which is approved by the FDA for the following indications: (1) for relief of the signs and symptoms of osteoarthritis; (2) for relief of the signs and symptoms of rheumatoid arthritis in adults; (3) for the management of acute pain in adults; (4) for the treatment of primary dysmenorrhea; (5) to reduce the number of adenomatous colorectal polyps in familial adenomatous polyposis (FAP) as an adjunct to usual care (e.g.,

endoscopic surveillance surgery); (6) for relief of signs and symptoms of ankylosing spondylitis; and (7) for relief of the signs and symptoms of juvenile rheumatoid arthritis in patients two years of age and older. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants deny that Celebrex® caused Plaintiffs injury or damage and deny the remaining allegations in this paragraph of the Complaint.

3. Answering the second unnumbered paragraph of Section II of the Complaint, Defendants admit that Plaintiffs claim to be Texas citizens. Defendants deny the remaining allegations in this paragraph of the Complaint.

4. Answering the third unnumbered paragraph in Section II of the Complaint, Defendants state that the allegations in this paragraph of the Complaint regarding Pfizer Inc. ("Pfizer") are not directed toward Defendants and, therefore, no response is required. To the extent that a response is deemed required, Defendants admit that Pfizer is a Delaware corporation with its principal place of business in New York, and that Pfizer does business in the State of Texas. Defendants admit that, during certain periods of time, Pfizer marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

5. Answering the fourth unnumbered paragraph in Section II of the Complaint, Defendants state that the allegations in this paragraph of the Complaint regarding Jacqueline Guerrero are not directed toward Defendants and, therefore, no response is required.

6. Answering the fifth unnumbered paragraph in Section II of the Complaint, Defendants state that the allegations in this paragraph of the Complaint regarding Bob Davis are not directed toward Defendants and, therefore, no response is required.

7. Answering the sixth unnumbered paragraph in Section II of the Complaint, Defendants admit that Jeanne L. Jalufka may be served with process at her place of residence.

8. Answering the seventh unnumbered paragraph in Section II of the Complaint, Defendants state that the allegations in this paragraph of the Complaint regarding Kyle M. Nelson are not directed toward Defendants and, therefore, no response is required.

9. Answering the eighth unnumbered paragraph in Section II of the Complaint, Defendants state that the allegations in this paragraph of the Complaint regarding Jason D. Hahn are not directed toward Defendants and, therefore, no response is required.

10. Answering the ninth unnumbered paragraph in Section II of the Complaint, Defendants admit that Robert G. Vial may be served with process in at his place of residence.

11. Answering the tenth unnumbered paragraph in Section II of the Complaint, Defendants state that the allegations in this paragraph of the Complaint regarding Katheryn K. Truitt are not directed toward Defendants and, therefore, no response is required.

12. Answering the eleventh unnumbered paragraph in Section II of the Complaint, Defendants state that the allegations in this paragraph of the Complaint regarding Kari A. McLuhan are not directed toward Defendants and, therefore, no response is required.

13. Answering the twelfth unnumbered paragraph in Section II of the Complaint, Defendants state that the allegations in this paragraph of the Complaint regarding Reynaldo Riojas are not directed toward Defendants and, therefore, no response is required.

14. Answering the thirteenth unnumbered paragraph in Section II of the Complaint, Defendants state that the allegations in this paragraph of the Complaint regarding Francisco Meza are not directed toward Defendants and, therefore, no response is required.

15. Answering the fourteenth unnumbered paragraph in Section II of the Complaint, Defendants state that the allegations in this paragraph of the Complaint regarding Jack Barineau are not directed toward Defendants and, therefore, no response is required.

16. Answering the fifteenth unnumbered paragraph in Section II of the Complaint, Defendants admit that Erica Zeplin may be served with process at her place of residence.

17. Answering the sixteenth unnumbered paragraph in Section II of the Complaint, Defendants state that the allegations in this paragraph of the Complaint regarding Deborah Quinones are not directed toward Defendants and, therefore, no response is required.

18. Answering the seventeenth unnumbered paragraph in Section II of the Complaint, Defendants state that the allegations in this paragraph of the Complaint regarding W. Lance Goodson are not directed toward Defendants and, therefore, no response is required.

19. Answering the eighteenth unnumbered paragraph in Section II of the Complaint, Defendants state that the allegations in this paragraph of the Complaint regarding Keeley Rodriguez are not directed toward Defendants and, therefore, no response is required.

20. Answering the nineteenth unnumbered paragraph in Section II of the Complaint, Defendants state that the allegations in this paragraph of the Complaint regarding Leah Silva are not directed toward Defendants and, therefore, no response is required.

21. Answering the twentieth unnumbered paragraph in Section II of the Complaint, Defendants state that the allegations in this paragraph of the Complaint regarding Daniel Ponce are not directed toward Defendants and, therefore, no response is required.

22. Answering the twenty-first unnumbered paragraph in Section II of the Complaint, Defendants state that the allegations in this paragraph of the Complaint regarding Celeste Escobar are not directed toward Defendants and, therefore, no response is required.

23. Answering the twenty-second unnumbered paragraph in Section II of the Complaint, Defendants state that the allegations in this paragraph of the Complaint regarding Jill Guidry are not directed toward Defendants and, therefore, no response is required.

24. Answering the twenty-third unnumbered paragraph in Section II of the Complaint, Defendants state that the allegations in this paragraph of the Complaint regarding Daniel Townsend are not directed toward Defendants and, therefore, no response is required.

25. Answering the twenty-fourth unnumbered paragraph in Section II of the Complaint, Defendants admit that Lynsey Adame may be served with process at her place of residence.

III.
Response to Allegations Regarding Jurisdiction and Venue

26. Answering the first unnumbered paragraph in Section III of the Complaint, Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants admit that Plaintiffs claim to be residents of the State of Texas. Defendants admit that Jeanne L. Jalufka, Robert G. Vial, Erica Zeplin, and Lynsey Adame are residents of the State of Texas. Defendants admit that Plaintiffs claim that the amount in controversy exceeds minimum jurisdictional limits. Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants no response is required. Defendants deny committing a tort within the State of Texas, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

27. Answering the second unnumbered paragraph in Section III of the Complaint, Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants are without knowledge or information sufficient to form a belief as the judicial district in which the asserted claims allegedly arose and, therefore, deny that venue is proper in Jim Wells County, Texas. Defendants

deny committing a tort within the State of Texas and deny the remaining allegations in this paragraph of the Complaint.

IV.
Response to Factual Allegations

28. Answering the first unnumbered paragraph in Section IV of the Complaint, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants state that the allegations in this paragraph of the Complaint regarding Pfizer are not directed toward Defendants, and, therefore, no response is required. To the extent that a response is deemed required, Defendants admit that, during certain periods of time, Pfizer marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny that Celebrex® caused Plaintiffs injury or damage and deny the remaining allegations in this paragraph of the Complaint.

29. Answering the second unnumbered paragraph in Section IV of the Complaint, Defendants admit that Celebrex® is in a class of drugs that is, at times, referred to as non-steroidal anti-inflammatory drugs ("NSAIDs"). Defendants state that Celebrex® is a prescription medication which is approved by the FDA for the following indications: (1) for relief of the signs and symptoms of osteoarthritis; (2) for relief of the signs and symptoms of rheumatoid arthritis in adults; (3) for the management of acute pain in adults; (4) for the treatment of primary dysmenorrhea; (5) to reduce the number of adenomatous colorectal polyps

in familial adenomatous polyposis (FAP) as an adjunct to usual care (e.g., endoscopic surveillance surgery); (6) for relief of signs and symptoms of ankylosing spondylitis; and (7) for relief of the signs and symptoms of juvenile rheumatoid arthritis in patients two years of age and older. Defendants deny the remaining allegations in this paragraph of the Complaint.

30. Answering the third unnumbered paragraph in Section IV of the Complaint, Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants admit that, during certain periods of time, Pfizer marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

31. Answering the fourth unnumbered paragraph in Section IV of the Complaint, Defendants state that, the allegations in this paragraph of the Complaint regarding Pfizer are not directed toward Defendants, and, therefore, no response is required. To the extent that a response is deemed required, Defendants admit that, during certain periods of time, Pfizer marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Celebrex® is a prescription medication which is approved by the FDA for the following indications: (1) for relief of the signs and symptoms of osteoarthritis; (2) for relief of the signs and symptoms of rheumatoid arthritis in adults; (3) for the management of acute pain in adults; (4) for the treatment of primary dysmenorrhea; (5) to reduce the number of adenomatous colorectal polyps in familial adenomatous polyposis (FAP) as an adjunct to usual care (e.g., endoscopic surveillance surgery); (6) for relief of signs and symptoms of ankylosing spondylitis; and (7) for relief of the signs and symptoms of juvenile rheumatoid arthritis in patients two years

of age and older. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

32. Answering the fifth unnumbered paragraph in Section IV of the Complaint, Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants admit that, during certain periods of time, Pfizer marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

33. Answering the sixth unnumbered paragraph in Section IV of the Complaint, Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants admit that, during certain periods of time, Pfizer marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

34. Answering the seventh unnumbered paragraph in Section IV of the Complaint, Defendants state that, the allegations in this paragraph of the Complaint regarding Pfizer are not directed toward Defendants, and, therefore, no response is required. To the extent that a response is deemed required, Defendants admit that, during certain periods of time, Pfizer marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare

providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

35. Answering the eighth unnumbered paragraph in Section IV of the Complaint, Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

36. Answering the ninth unnumbered paragraph in Section IV of the Complaint, Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

37. Answering the tenth unnumbered paragraph in Section IV of the Complaint, Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants deny the allegations in this paragraph of the Complaint.

38. Answering the eleventh unnumbered paragraph in Section IV of the Complaint, Defendants are without knowledge or information sufficient to form a belief as to the truth of the

allegations regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants state that the referenced press release and study speak for themselves and respectfully refer the Court to the press release and study for their actual language and text. Any attempt to characterize the press release and study is denied. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

39. Answering the twelfth unnumbered paragraph in Section IV of the Complaint, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

40. Answering the thirteenth unnumbered paragraph in Section IV of the Complaint, Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not

directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants admit that they are or were employed by Pfizer as pharmaceutical sales representatives and, at times, called on certain healthcare providers regarding Pfizer's products. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

41. Answering the fourteenth unnumbered paragraph in Section IV of the Complaint, Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

V.

Response to First Cause of Action: Strict Products Liability Failure to Warn

42. Answering the first unnumbered paragraph in Section V of the Complaint, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants admit that, during certain periods of time, Pfizer marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that, in the ordinary case, Celebrex® was expected to reach users and consumers without substantial change from the time of sale. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the remaining allegations in this paragraph of the Complaint.

43. Answering the second unnumbered paragraph in Section V of the Complaint, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is defective, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

44. Answering the third unnumbered paragraph in Section V of the Complaint, Defendants state that, the allegations in this paragraph of the Complaint regarding Pfizer are not directed toward Defendants, and, therefore, no response is required. To the extent that a response is deemed required, Defendants deny the allegations in this paragraph of the Complaint.

45. Answering the fourth unnumbered paragraph in Section V of the Complaint, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

46. Answering the fifth unnumbered paragraph in Section V of the Complaint, Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex®

were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants state that Celebrex® is a prescription medication which is approved by the FDA for the following indications: (1) for relief of the signs and symptoms of osteoarthritis; (2) for relief of the signs and symptoms of rheumatoid arthritis in adults; (3) for the management of acute pain in adults; (4) for the treatment of primary dysmenorrhea; (5) to reduce the number of adenomatous colorectal polyps in familial adenomatous polyposis (FAP) as an adjunct to usual care (e.g., endoscopic surveillance surgery); (6) for relief of signs and symptoms of ankylosing spondylitis; and (7) for relief of the signs and symptoms of juvenile rheumatoid arthritis in patients two years of age and older. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

47. Answering the sixth unnumbered paragraph in Section V of the Complaint, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants deny any wrongful conduct, deny that Celebrex® is defective, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

48. Answering the seventh unnumbered paragraph in Section V of the Complaint, Defendants state that, the allegations in this paragraph of the Complaint regarding Pfizer are not directed toward Defendants, and, therefore, no response is required. To the extent that a response is deemed required, Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential

effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

49. Answering the eighth unnumbered paragraph in Section V of the Complaint, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is defective or unreasonably dangerous, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

VI.

Response to Second Cause of Action: Strict Products Liability Defective Product

50. Answering the first unnumbered paragraph in Section VI of the Complaint, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants admit that, during certain periods of time, Pfizer marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state

that, in the ordinary case, Celebrex® was expected to reach users and consumers without substantial change from the time of sale. Defendants deny the remaining allegations in this paragraph of the Complaint.

51. Answering the second unnumbered paragraph in Section VI of the Complaint, Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is defective or unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint.

52. Answering the third unnumbered paragraph in Section VI of the Complaint, Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is defective or unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint.

53. Answering the fourth unnumbered paragraph in Section VI of the Complaint, Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required,

Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the remaining allegations in this paragraph of the Complaint.

54. Answering the fifth unnumbered paragraph in Section VI of the Complaint, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is defective or unreasonably dangerous, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

55. Answering the sixth unnumbered paragraph in Section VI of the Complaint, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants state that Celebrex® was and is safe and effective when used in accordance with its

FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is defective or unreasonably dangerous, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

56. Answering the seventh unnumbered paragraph in Section VI of the Complaint, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

57. Answering the eighth unnumbered paragraph in Section VI of the Complaint, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is defective or unreasonably dangerous, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

VII.
Response to Third Cause of Action: Negligence

58. Answering the first unnumbered paragraph in Section VII of the Complaint, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is unreasonably dangerous, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

59. Answering the second unnumbered paragraph in Section VII of the Complaint, Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

60. Answering the third unnumbered paragraph in Section VII of the Complaint, Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed

toward Defendants, no response is required. To the extent that a response is deemed required, Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

61. Answering the fourth unnumbered paragraph in Section VII of the Complaint, Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

62. Answering the fifth unnumbered paragraph in Section VII of the Complaint, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all

times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

63. Answering the sixth unnumbered paragraph in Section VII of the Complaint, Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

VIII.
Response to Fourth Cause of Action: Breach of Implied Warranty

64. Answering the first unnumbered paragraph in Section VIII of the Complaint, Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required,. Defendants admit that, during certain periods of time, Pfizer marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

65. Answering the second unnumbered paragraph in Section VIII of the Complaint, Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit that Pfizer provided FDA-approved prescribing information regarding Celebrex®. Defendants deny the remaining allegations in this paragraph of the Complaint.

66. Answering the third unnumbered paragraph in Section VIII of the Complaint, Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

67. Answering the fourth unnumbered paragraph in Section VIII of the Complaint, Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

IX.
Response to Fifth Cause of Action: Breach of Express Warranty

68. Answering the first unnumbered paragraph in Section IX of the Complaint, Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants admit that, during certain periods of time, Pfizer marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved

prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit that Pfizer provided FDA-approved prescribing information regarding Celebrex®. Defendants deny the remaining allegations in this paragraph of the Complaint.

69. Answering the second unnumbered paragraph in Section IX of the Complaint, Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit that Pfizer provided FDA-approved prescribing information regarding Celebrex®. Defendants deny the remaining allegations in this paragraph of the Complaint.

70. Answering the third unnumbered paragraph in Section IX of the Complaint, Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

71. Answering the fourth unnumbered paragraph in Section IX of the Complaint, Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed

toward Defendants, no response is required. To the extent that a response is deemed required, Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit that Pfizer provided FDA-approved prescribing information regarding Celebrex®. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

72. Answering the fifth unnumbered paragraph in Section IX of the Complaint, Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

73. Answering the sixth unnumbered paragraph in Section IX of the Complaint, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

X.
Response to Sixth Cause of Action: Fraud

74. Answering the first unnumbered paragraph in Section X of the Complaint, Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

75. Answering the second unnumbered paragraph in Section X of the Complaint, Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

76. Answering the third unnumbered paragraph in Section X of the Complaint, Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed

toward Defendants, no response is required. To the extent that a response is deemed required, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

77. Answering the fourth unnumbered paragraph in Section X of the Complaint, Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

78. Answering the fifth unnumbered paragraph in Section X of the Complaint, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

79. Answering the sixth unnumbered paragraph in Section X of the Complaint, Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

80. Answering the seventh unnumbered paragraph in Section X of the Complaint, Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

XI.
Response to Seventh Cause of Action: Fraud by Concealment

81. Answering the first unnumbered paragraph in Section XI of the Complaint, Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the remaining allegations in this paragraph of the Complaint.

82. Answering the second unnumbered paragraph in Section XI of the Complaint, Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

83. Answering the third unnumbered paragraph in Section XI of the Complaint, Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

84. Answering the fourth unnumbered paragraph in Section XI of the Complaint, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times

adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

85. Answering the fifth unnumbered paragraph in Section XI of the Complaint, Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

86. Answering the sixth unnumbered paragraph in Section XI of the Complaint, Defendants state that, to the extent that the allegations in this paragraph of the Complaint are not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

XII.
Response to Allegations Regarding Malice

87. Answering the first unnumbered paragraph in Section XII of the Complaint, Defendants state that, to the extent that the allegations in this paragraph of the Complaint not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex®

were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

XIII.

88. Answering the first unnumbered paragraph in Section XIII of the Complaint, Defendants state that, to the extent that the allegations in this paragraph of the Complaint not directed toward Defendants, no response is required. To the extent that a response is deemed required, Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to Prayer for Relief

89. Defendants deny that they are liable to Plaintiffs for any type of damages, in any amount, and further deny the remaining allegations in this paragraph of the Complaint, including all subparts.

GENERAL DENIAL

Defendants deny all allegations and/or legal conclusions set forth in Plaintiffs' Complaint that have not been previously admitted, denied, or explained.

AFFIRMATIVE DEFENSES

Defendants reserve the right to rely upon any of the following or additional defenses to claims asserted by Plaintiffs to the extent that such defenses are supported by information developed through discovery or evidence at trial. Defendants affirmatively show that:

First Defense

1. Plaintiffs' Petition fails to state a claim against Defendants upon which relief can be granted.

Second Defense

2. Plaintiffs' causes of action are barred in whole or in part by the applicable statute of limitations and/or statute of repose.

Third Defense

3. Plaintiffs' claims against Defendants are barred under Section 20, comment g of the Restatement (Third) of Torts: Products Liability.

Fourth Defense

4. Plaintiffs' causes of action are barred and/or preempted by Chapter 82 of the Texas Civil Practice & Remedies Code, including but not limited to §§ 82.001, 82.003, and 82.007.

Fifth Defense

5. Plaintiffs' causes of action are barred by Texas Civil Practice & Remedies Code § 16.012.

Sixth Defense

6. Plaintiffs' causes of action are barred in whole or in part by the doctrines of laches, waiver and/or estoppel.

Seventh Defense

7. Plaintiffs' recovery, if any, is barred entirely, or should be reduced, by Plaintiffs' comparative negligence.

Eighth Defense

8. The damages alleged by Plaintiffs were caused, solely or partially, or proximately caused by some person or third party for whom Defendants are not legally responsible.

Ninth Defense

9. This action is subject to the proportionate responsibility provisions of Chapter 33 of the Texas Civil Practice and Remedies Code, including (without limitation) the requirement of § 33.003 thereof that the trier of fact determine the relative responsibility of each claimant, defendant, and responsible third-party that may be joined in the suit.

Tenth Defense

10. If Plaintiffs settle with any other person or entity, then Defendants reserve the right to make a written election of credit for settlements under § 33.014 of the Texas Civil Practice and Remedies Code.

Eleventh Defense

11. Plaintiffs' alleged damages resulted from new and independent, unforeseeable, superseding and/or intervening causes unrelated to any conduct of Defendants.

Twelfth Defense

12. Plaintiffs' alleged damages were not proximately caused by any act or omission of Defendants.

Thirteenth Defense

13. The producing causes of the damages Plaintiffs allegedly suffered were acts or omissions of some person, cause or entity other than Defendants.

Fourteenth Defense

14. Plaintiffs' alleged damages were the result of pre-existing and/or unrelated conditions that were independent of, or far removed from, any conduct of Defendants.

Fifteenth Defense

15. Defendants affirmatively plead that Plaintiffs cannot recover under a product liability theory against them because they are not in the business of manufacturing, assembling, selling, or distributing any product at issue. Without waiving said defense, Plaintiffs' damages, if any, were caused by changes and/or alterations to the product at issue made by persons not within Defendants' control.

Sixteenth Defense

16. Defendants affirmatively plead that Plaintiffs cannot recover under a product liability theory against them because they are not in the business of manufacturing, assembling, selling, or distributing any product at issue. Without waiving said defense, the methods, standards, and techniques utilized with respect to the manufacture, design, and marketing of the Celebrex®, if

any, used in this case, included adequate warnings and instructions with respect to the product's use in the package insert and other literature, and conformed to the generally recognized, reasonably available, and reliable state of the knowledge at the time the product was marketed.

Seventeenth Defense

17. Defendants affirmatively plead that Plaintiffs cannot recover under a product liability theory against them because they are not in the business of manufacturing, assembling, selling, or distributing any product at issue. Without waiving said defense, Plaintiffs' claims are barred because Celebrex® was designed, tested, manufactured and labeled in accordance with the state-of-the art industry standards existing at the time of the sale.

Eighteenth Defense

18. Defendants affirmatively plead that Plaintiffs cannot recover under a product liability theory against them because they are not in the business of manufacturing, assembling, selling, or distributing any product at issue. Without waiving said defense and based on the state of scientific, medical, and technological knowledge at the time that Celebrex® was marketed, Celebrex® was reasonably safe for its normal and foreseeable use at all relevant times.

Nineteenth Defense

19. Defendants affirmatively plead that Plaintiffs cannot recover under a product liability theory against them because they are not in the business of manufacturing, assembling, selling, or distributing any product at issue. Without waiving said defense, any claims by Plaintiffs for inadequate warnings are controlled by, and barred under, the learned intermediary doctrine.

Twentieth Defense

20. Defendants affirmatively plead that Plaintiffs cannot recover under a product liability theory against them because they are not in the business of manufacturing, assembling, selling, or distributing any product at issue. Without waiving said defense, Plaintiffs' claims are governed, in whole or in part, by Sections 2 and 4 of the Restatement (Third) of Torts: Product Liability (including the comments thereto) because Defendants complied with all applicable statutes and with the requirements and regulations of the Food and Drug Administration.

Twenty-first Defense

21. Defendants affirmatively plead that Plaintiffs cannot recover under a product liability theory against them because they are not in the business of manufacturing, assembling, selling, or distributing any product at issue. Without waiving said defense, Plaintiffs' claims against Defendants are barred under Section 402A, comments j and/or k of the Restatement (Second) of Torts.

Twenty-second Defense

22. Defendants affirmatively plead that Plaintiffs cannot recover under a product liability theory against them because they are not in the business of manufacturing, assembling, selling, or distributing any product at issue. Without waiving said defense, Plaintiffs' claims against Defendants are barred under Sections 2, 4, and 6 *et seq*. of the Restatement (Third) of Torts: Product Liability. Alternatively, Plaintiffs' claims are barred because the product's benefits outweighed its risks.

Twenty-third Defense

23. Defendants affirmatively plead that Plaintiffs cannot recover under a product liability theory against them because they are not in the business of manufacturing, assembling, selling, or distributing any product at issue. Without waiving said defense, Plaintiffs' claims are barred in whole or in part because Celebrex® "provides net benefits for a class of patients" within the meaning of comment f to Section 6 of the Restatement (Third) of Torts: Product Liability.

Twenty-fourth Defense

24. Defendants affirmatively plead that Plaintiffs cannot recover under a product liability theory against them because they are not in the business of manufacturing, assembling, selling, or distributing any product at issue. Without waiving said defense, Plaintiffs' claims are barred, in whole or in part, by the doctrine of accord and satisfaction.

Twenty-fifth Defense

25. Defendants affirmatively plead that Plaintiffs cannot recover under a product liability theory against them because they are not in the business of manufacturing, assembling, selling,

or distributing any product at issue. Without waiving said defense, Plaintiffs' claims are barred in whole or in part because any alleged defect was not known or not reasonably scientifically knowable at the time the product was distributed.

Twenty-sixth Defense

26. To the extent that Plaintiffs' claims are based on a theory providing for liability without proof of causation, the claims violate Defendants' rights under the United States Constitution.

Twenty-seventh Defense

27. Plaintiffs' claims are barred, in whole or in part, because Plaintiffs did not incur any ascertainable loss as a result of Defendants' conduct.

Twenty-eighth Defense

28. The damages, if any, recoverable by Plaintiffs must be reduced by any amount of damages legally caused by Plaintiffs' failure to mitigate such damages in whole or in part.

Twenty-ninth Defense

29. Plaintiffs' claims are barred in whole or in part by the unforeseeable product misuse and/or abnormal or unintended use of the product.

Thirtieth Defense

30. Plaintiffs' claims are barred by Plaintiffs' failure to comply with conditions precedent to the right to recover.

Thirty-first Defense

31. Plaintiffs' claims are barred because Defendants' conduct is not the producing cause, a proximate cause, or a cause-in-fact of Plaintiffs' alleged injuries.

Thirty-second Defense

32. Plaintiffs' claims are barred in whole or in part by intervening and/or superseding acts.

Thirty-third Defense

33. Plaintiffs' claims are barred in whole or in part by the assumption of the risk associated with the purchase and/or use of the product.

Thirty-fourth Defense

34. Plaintiffs' claims are barred in whole or in part by the failure to heed warnings and/or failure to follow instructions.

Thirty-fifth Defense

35. Plaintiffs' claims are barred in whole or in part by the doctrine of informed consent. Plaintiffs were informed of the risks associated with treatment and willingly consented to treatment despite those risks. Specifically, Plaintiffs gave informed consent to the prescribing physician before taking Celebrex®, alone or in combination with any other drug(s).

Thirty-sixth Defense

36. Plaintiffs' injuries, if any, were caused by an idiosyncratic reaction to the product.

Thirty-seventh Defense

37. The duty to obtain Plaintiffs' informed consent prior to prescribing Celebrex®, alone or in combination with any other drug(s), rested solely with the prescribing physicians.

Thirty-eighth Defense

38. Plaintiffs may not assert a claim against Defendants for negligent misrepresentation as Plaintiffs did not suffer a pecuniary loss as a result of any alleged misrepresentation by Defendants.

Thirty-ninth Defense

39. Plaintiffs' claims of negligent misrepresentation are barred by the failure to justifiably rely on any alleged misrepresentation of Defendants.

Fortieth Defense

40. Plaintiffs' claims of misrepresentation are barred because any alleged misrepresentation on which Plaintiffs relied did not constitute a misrepresentation of material facts.

Forty-first Defense

41. Plaintiffs' claims of fraud are barred by reason of Plaintiffs' failure to allege circumstances constituting fraud with particularity, as required under both the state and federal rules.

Forty-second Defense

42. Defendants affirmatively plead that Plaintiffs cannot recover under a product liability theory against them because they are not in the business of manufacturing, assembling, selling, or distributing any product at issue. Without waiving said defense, Plaintiffs did not rely on any alleged express or implied warranty.

Forty-third Defense

43. Defendants affirmatively plead that Plaintiffs cannot recover under a product liability theory against them because they are not in the business of manufacturing, assembling, selling, or distributing any product at issue. Without waiving said defense, Plaintiffs failed to notify Defendants of any alleged breach of warranty within a reasonable time after she discovered or should have discovered any such alleged breach and is, therefore, barred from any recovery for such claims.

Forty-fourth Defense

44. Defendants affirmatively plead that Plaintiffs cannot recover under a product liability theory against them because they are not in the business of manufacturing, assembling, selling, or distributing any product at issue. Without waiving said defense, Plaintiffs' claims for breach of warranty are barred in whole or in part by the relevant disclaimers.

Forty-fifth Defense

45. Defendants affirmatively plead that Plaintiffs cannot recover under a product liability theory against them because they are not in the business of manufacturing, assembling, selling, or distributing any product at issue. Without waiving said defense, Plaintiffs' claims for breach of warranty are barred in whole or in part because they are not in privity with Defendants.

Forty-sixth Defense

46. Defendants affirmatively plead that Plaintiffs cannot recover under a product liability theory against them because they are not in the business of manufacturing, assembling, selling, or distributing any product at issue. Without waiving said defense, Defendants assert the

defenses of expiration, limitation, and exclusion to any applicable express or implied warranty, if any be proved.

Forty-seventh Defense

47. Defendants affirmatively plead that Plaintiffs cannot recover under a product liability theory against them because they are not in the business of manufacturing, assembling, selling, or distributing any product at issue. Without waiving said defense, Plaintiffs' claims are barred in whole or in part because any warranties, if made, are excluded through course of dealing, course of performance, and/or usage of trade.

Forty-eighth Defense

48. Defendants expressly deny that any third party engaging in the acts alleged by Plaintiffs were acting as Defendants' agent or servant, at the instruction of Defendants, or within the Defendants' control. Therefore, Plaintiffs' claims, to the extent they seek recovery for the acts or omissions of such third parties, are barred in whole or in part as a matter of law.

Forty-ninth Defense

49. Defendants affirmatively plead that Plaintiffs cannot recover under a product liability theory against them because they are not in the business of manufacturing, assembling, selling, or distributing any product at issue. Without waiving said defense, Plaintiffs' claims are barred, in whole or in part, because the manufacturing, labeling, packaging, and any advertising of the product complied with the applicable codes, standards and regulations established, adopted, promulgated or approved by any applicable regulatory body, including but not limited to the United States, any state, and any agency thereof.

Fiftieth Defense

50. Defendants affirmatively plead that Plaintiffs cannot recover under a product liability theory against them because they are not in the business of manufacturing, assembling, selling, or distributing any product at issue. Without waiving said defense, Plaintiffs' claims are barred in whole or in part by the doctrine of federal preemption. The manufacture, marketing, and labeling of Celebrex® was and is controlled by federal law, and the conduct relating to the product at

issue was at all times in compliance and obedience with applicable federal law. If Plaintiffs' causes of action against Defendants are permitted and allowed, they would impede, impair, interfere with, frustrate and/or burden the effectiveness of federal law regulating the field of prescription drugs and would constitute an invalid burden on interstate commerce, violating the supremacy and commerce clauses of the United States Constitution, Article VI, Section 2 and Article I, Section 8, respectively, as set forth in *Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341 (2001). Plaintiffs' claims, in whole or in part, are preempted, or barred by applicable federal law, including any claim based in whole or in part on:

(a) any allegation of negligence *per se* or that Defendants violated federal regulations, including any regulations promulgated or enforced by the Food and Drug Administration;

(b) any allegation that Defendants committed "fraud" on, or otherwise misled, made misrepresentations to, concealed material information from, or violated reporting requirements imposed by any agency of the federal government, including the Food and Drug Administration;

(c) any allegation that Celebrex® was not "safe and effective" or that the risks of the drug outweighed its benefits;

(d) any allegation that Defendants failed to give Plaintiffs' healthcare providers adequate warnings concerning the risks associated with Celebrex®; and/or

(e) any allegation that, if accepted, would impose standards of care in addition to, or different from, those imposed by federal law, including federal regulations promulgated by the Food and Drug Administration.

Fifty-first Defense

51. Defendants affirmatively plead that Plaintiffs cannot recover under a product liability theory against them because they are not in the business of manufacturing, assembling, selling, or distributing any product at issue. Without waiving said defense, Plaintiffs' claims are barred, in whole or in part, by the doctrine of abstention in that the common law gives deference to discretionary actions by the United States Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act.

Fifty-second Defense

52. Defendants affirmatively plead that Plaintiffs cannot recover under a product liability theory against them because they are not in the business of manufacturing, assembling, selling, or distributing any product at issue. Without waiving said defense, Plaintiffs' claims are barred, in whole or in part, by the doctrines of primary jurisdiction and exhaustion of administrative remedies, because the FDA has exclusive or primary jurisdiction over the matters asserted in the Petition.

Fifty-third Defense

53. The standards in Texas governing the award and review of damages for non-pecuniary damages, including damages for mental anguish and pain and suffering, are impermissibly vague or simply non-existent, and are inadequate to ensure that such awards do not include amounts intended as exemplary damages, which are impermissible in a compensatory damages award.

Fifty-fourth Defense

54. Plaintiffs' claims for non-pecuniary damages are unconstitutionally vague and/or overbroad, and are in contravention of Defendants' rights under each of the following constitutional provisions:

(a) the Due Process Clause of the Fifth and Fourteenth Amendments of the United States Constitution;

(b) the Takings Clause of the Fifth Amendment of the United States Constitution;

(c) the Excessive Fines Clause of the Eighth Amendment of the United States Constitution;

(d) the Equal Protection Clause of the Fourteenth Amendment; as well as the various provisions of the Texas Constitution, including but not limited to art. I '' 3, 13, 14, 16 and 19.

Fifty-fifth Defense

55. As set forth in *BMW of North America v. Gore*, 517 U.S. 559 (1996), *State Farm Mutual Automobile Ins. Co. v. Campbell*, 538 U.S. 408 (2003) and *Philip Morris USA v. Williams*, 127

S. Ct. 1057 (2007), the Due Process Clause of the United States Constitution protects Defendants from any award of damages that:

(a) is based, in whole or in part, on conduct which did not harm the Plaintiffs;

(b) is based, in whole or in part, on conduct and/or harm that occurred wholly outside Texas;

(c) is based, in whole or in part, on conduct that is the exclusive province of federal law;

(d) is based, in whole or in part, on comparisons of the relative wealth of Defendants and Plaintiffs; or

(e) is grossly disproportionate to the harm suffered by Plaintiffs.

Because the standards in Texas governing the award and review of damages for non-pecuniary damages, including damages for mental anguish and pain and suffering, are impermissibly vague or simply non-existent, they are inadequate to ensure that such awards are not based on impermissible considerations. Any award of non-pecuniary damages in this case would therefore be in contravention of the Due Process standards set forth in *BMW of North America v. Gore*, 517 U.S. 559 (1996), *State Farm Mutual Automobile Ins. Co. v. Campbell*, 538 U.S. 408 (2003), and *Philip Morris USA v. Williams*, 127 S. Ct. 1057 (2007).

Fifty-sixth Defense

56. Plaintiffs' claims for punitive or exemplary damages are subject to the limitations and requirements of Chapter 41 of the Texas Civil Practice and Remedies Code, including the cap on exemplary damages set out in Section 41.008(b).

Fifty-seventh Defense

57. Plaintiffs' claims for punitive damages are in contravention of Defendants' rights under each of the following constitutional provisions:

(a) the Commerce Clause of Article I, Section 8 of the United States Constitution;

(b) the Contracts Clause of Article I, Section 10 of the United States Constitution;

(c) the prohibition against *ex post facto* laws embodied in Article I, Section 10 of the United States Constitution;

(d) the Supremacy Clause of Article VI of the United States Constitution;

(e) the Free Speech Clause of the First Amendment of the United States Constitution;

(f) the Due Process Clause of the Fifth and Fourteenth Amendments of the United States Constitution;

(g) the Takings Clause of the Fifth Amendment of the United States Constitution;

(h) the Right to Counsel of the Sixth Amendment of the United States Constitution;

(i) the Excessive Fines Clause of the Eighth Amendment of the United States Constitution;

(j) the Right to Trial by Jury contained in the Seventh Amendment of the United States Constitution;

(k) the Equal Protection Clause of the Fourteenth Amendment;

(l) as well as the various provisions of the Texas Constitution, including but not limited to Art. I. §§ 3, 13, 14, 16, and 19.

Fifty-eighth Defense

58. Because of the lack of clear standards, the imposition of punitive damages against Defendants is unconstitutionally vague and/or overbroad.

Fifty-ninth Defense

59. No act or omission of Defendants was malicious, willful, wanton, reckless or grossly negligent and, therefore, any award of punitive damages is barred.

Sixtieth Defense

60. Defendants affirmatively plead that Plaintiffs cannot recover under a product liability theory against them because they are not in the business of manufacturing, assembling, selling, or distributing any product at issue. Without waiving said defense and to the extent Plaintiffs' claim for punitive damages is premised on alleged violations of FDA regulations, such claim is preempted by federal law and by the authority set out in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001).

Sixty-first Defense

61. With respect to Plaintiffs' demand for punitive damages, Defendants specifically incorporate by reference any and all standards or limitations regarding the determination and enforceability of punitive damage awards which arose in the decisions of *BMW of North America v. Gore*, 517 U.S. 559 (1996) and *State Farm Mutual Automobile Ins. Co. v. Campbell*, 538 U.S. 408 (2003).

Sixty-second Defense

62. Defendants reserve the right to supplement their assertion of defenses as they continue with their factual investigation of Plaintiffs' claims.

JURY DEMAND

Defendants hereby demand a trial by jury.

CONSENT TO REMOVAL

Defendants were served with citation in this case after it was removed to federal court. As such, Defendants' consent to removal is not required. Nevertheless, Defendants consent to the removal of this case to this Court.

PRAYER

WHEREFORE, Defendants pray that Plaintiffs take nothing by their suit, that Defendants be discharged with their costs expended in this matter, and for such other and further relief to which Defendants may be justly entitled.

Respectfully submitted,

CLARK, THOMAS & WINTERS,
A PROFESSIONAL CORPORATION
P.O. Box 1148
Austin, Texas 78767
(512) 472-8800
(512) 474-1129 - Fax

By: */s/ Kenneth J. Ferguson**
Kenneth J. Ferguson
Lead Attorney
State Bar No. 06918100
Email: kjf@ctw.com

*Signed with permission by Leslie A. Benitez

OF COUNSEL:

CLARK, THOMAS & WINTERS
A PROFESSIONAL CORPORATION
Leslie A. Benitez
State Bar No. 02134300
Email: lab@ctw.com
Kelly R. Kimbrough
State Bar No. 00794984
Email: krk@ctw.com
J. Andrew Hutton
State Bar No. 24012878
Email: ah1@ctw.com
P.O. Box 1148
Austin, Texas 78767
(512) 472-8800
(512) 474-1129 - Fax

ATTORNEYS FOR DEFENDANTS

CERTIFICATE OF SERVICE

I hereby certify that the foregoing document has been filed electronically on the 22nd day of June, 2007, and is available for viewing and downloading from the ECF system. Notice of Electronic Case Filing has been sent automatically to all parties listed in the Service List in effect on the date of electronic filing, which constitutes service of same, and satisfies the requirements of Fed. R. Civ. P. 5(b)(2)(D). Service on those parties who are not known to be users of the electronic filing system of the Southern District of Texas was accomplished in the manner listed below on June 22, 2007.

/s/ Leslie A. Benitez